Biosafety and Biosecurity Regulations in Germany

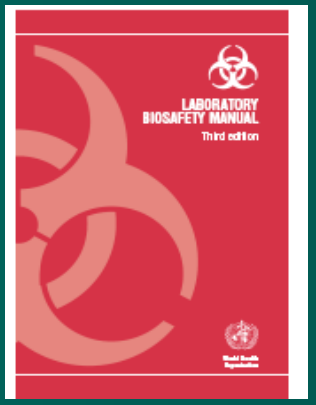
Peter Kämpfer

Justus-Liebig-University Giessen, Germany

Biosafety and Biosecurity - Definitions

Laboratory biosafety **describes containment principles, technologies and practices implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release.**

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

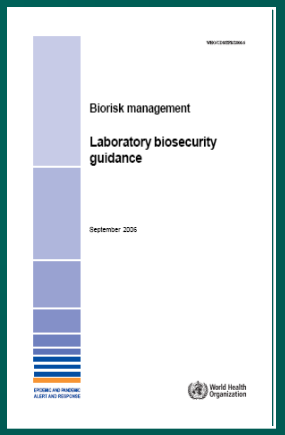


'Protect people from pathogens'

Prevention of accidental or 'deliberate' release from laboratories

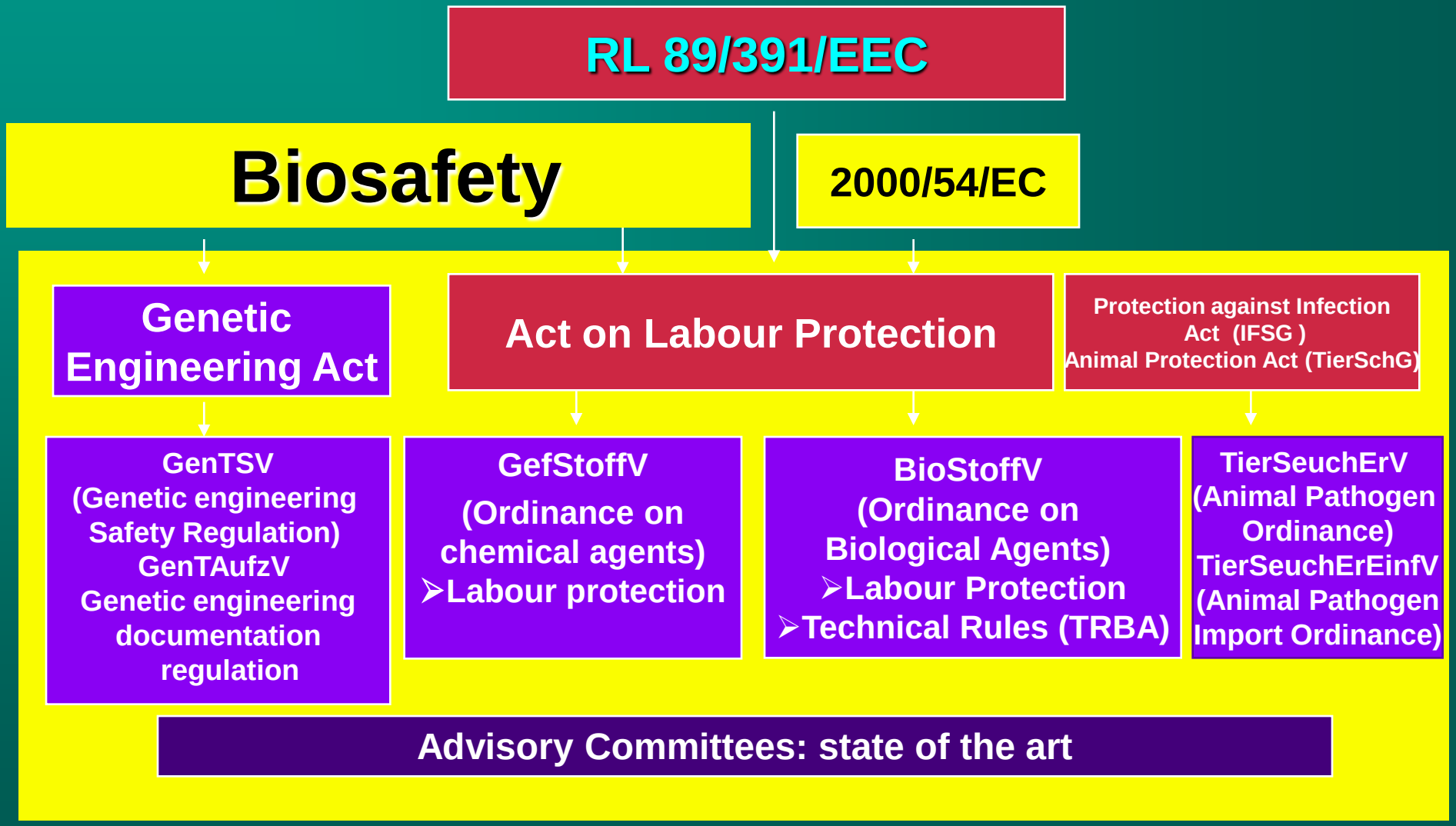
Laboratory biosecurity **describes the protection, control and accountability for valuable biological materials (VBM) within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release.**

http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html



'Protect pathogens from people'

European and German Legislation „Biosafety“



Directive 2000/54/EC - Classification

- Classification into four risk groups, according to their level of risk of infection
- Criteria of classification:
  - potential to cause human infectious diseases
  - hazard to workers
  - spreading or not to the community
  - possibilities of prevention and treatment

Directive 2000/54/EC

Definition of risk group (RG)

RG 1: unlikely to cause human disease

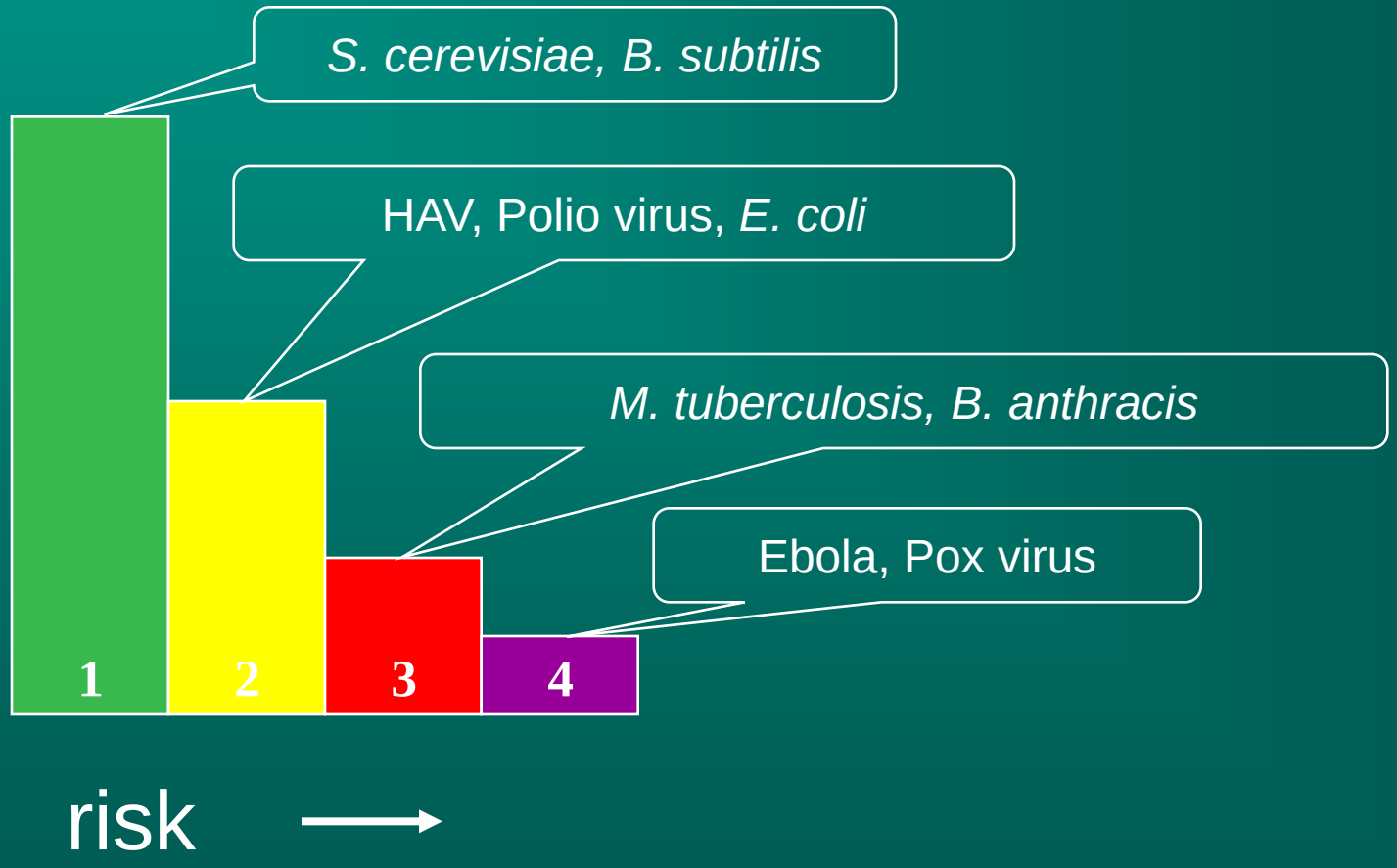
RG 2: can cause human disease, might be a hazard to workers, unlikely to spread to the community, effective prophylaxis or treatment available

RG 3: can cause severe human disease, present a serious hazard to workers, may present a risk of spreading to the community, usually effective prophylaxis or treatment available

RG 4: causes severe human disease, is a serious hazard to workers, may present a high risk of spreading to the community, usually no effective prophylaxis or treatment available

Risk groups consider only the ability to cause infectious diseases!

Classification – Risk Potential



Classification - Demands on Member States

- If there exists no community classification **member states shall classify** biological agents according to directive 2000/54/EG
- problem
  - only general requirements in directive 2000/54/EG
  - no scientific criteria for the classification of biological agents established
- Member states have to develop criteria for classification according to directive 2000/54/EG

Classification of biological agents into risk groups according to Technical Rule 450

- Systematics
- Metabolic properties
- Habitat, Mode of living
- Pathogenicity for humans virulence, factors of pathogenicity, mechanisms,
- Clinical picture
- Infectious dose, index of contagion, infectivity, manifestation
- Possibilities of treatment, prophylaxis, diagnosis
- Interactions with other organisms
- Mechanisms and routes of transmissions, entry, dispersal, excretion
- Epidemiology, Reservoirs of pathogens, sources of infection, geographic distribution
- Frequency of disease, distrubution,
- Resistance, tenacity

- http://www.baua.de/en/Topics-from-A-to-Z/Biological-Agents/TRBA/pdf/TRBA-450.pdf?__blob=publicationFile

Biological agents ordinance

Risk assessment - specific activities

Specific activities with biological agents of

- **risk group 1 → general hygiene measures**
- **risk group 2 → safety level 2**
- **risk group 3 → safety level 3**
- **risk group 4 → safety level 4**

➔ **containment measures according to annex II and III or the corresponding technical rules resp.**

Biosafety – Protection Level Concept according to Technical Rule 100 (Protective Measures for Specific and Non-specific Activities involving Biological Agents in Laboratories

- **Protection Level 1:**
  - General hygiene procedures

- **Protection Level 2:**
  - Restricted access
  - Specific disinfection procedures
  - Surface impervious to water and easy to clean benches
  - Safe storage of biological agents
  - Use of safety cabinets for work with pathogens that can be transmitted by air

http://www.baua.de/en/Topics-from-A-to-Z/Biological-Agents/TRBA/pdf/TRBA-100.pdf?__blob=publicationFile

Biosafety – Protection Level Concept according to Technical Rule 100 (Protective Measures for Specific and Non-specific Activities involving Biological Agents in Laboratories

- **Protection Level 3:** Protection Level 2 and in addition:
  - Workplace is to be separated from any other activities in the same building
  - High-efficiency particulate filter for exhaust air
  - Permanent negative air pressure at the workplace
  - Airlock with two self-closing and mutually interlocked doors
  - Vector control
  - Surface impervious to water and easy to clean benches and floors
  - Surfaces resistant to acids, alkalis, solvents and desinfectants
  - Observation window
  - Safety work bench of class 2
  - An autoclave must be available in the laboratory
  - Obligatory disinfection of any waste water arising in the working area
  - Incinerator for disposal of animal carcases has to be available

Biosafety – Protection Level Concept according to Technical Rule 100 (Protective Measures for Specific and Non-specific Activities involving Biological Agents in Laboratories

- **Protection Level 4:** Protection Level 3 and in addition:
  - High-performance particulate filters for feed air and exhaust air
  - Workplace must be capable of being sealed hermetically for the purpose of fumigation
  - staggered vacuum which increases towards the laboratory
  - 4-chamber airlock system with chambers for decontamination of full-protective suits
  - Safe storage of biological agents
  - Infected material including any animal is to be handled in a safety cabinet or isolation or other suitable containment
  - If necessary, an incinerator for disposal of animal carcases has to be present in the laboratory

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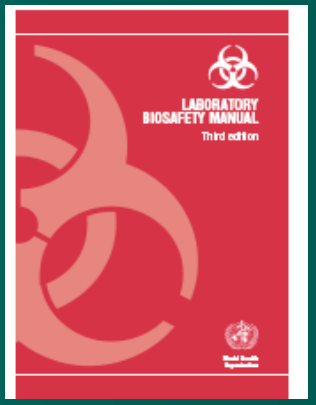

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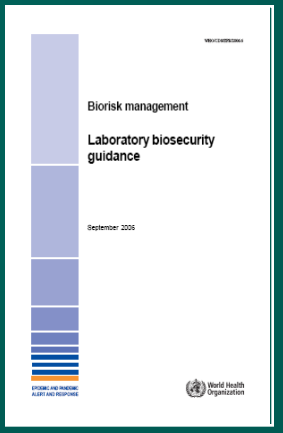

'Protect pathogens from people'

- **● Biosecurity (in the context of)**

- - 2001 Anthrax-Letters
- - Terrorism

Context: Agreement on Biological weapons

- National mechanisms to establish and maintain the security and oversight of pathogenic microorganisms and toxins (BWC/CONF.V/17) [2001/2002]
- Biosecurity has become a major international issue and the Expert Group should recommend that the Annual Meeting of States Parties urge expansion of existing biosecurity guidelines by the World Health Organization (WHO), Office Internationale des Epizooties (OIE), and the Food and Agriculture Organization (FAO). (BWC/MSP.2003/MX/WP.5 *[US Working paper]*)

EU CBRN Action Plan (1)

- EU Green Paper on Bio-preparedness (July 2007)
- CBRN Task Force: 2008 – 2009
- Task Force Report: January 2009 *(264 measures)*
- CBRN Action Plan: November 2009 *(83 bio measures)*
- Action Plan structure:
  - Areas: *Chem, Bio, Rad/Nuc*
  - Fields: *Prevention, Detection, Preparedness and Response*
- Implementation of the Action Plan is a responsibility of the EU Member States with support by the EU Commission

http://register.consilium.europa.eu/pdf/en/09/st15/st15505-re01.en09.pdf

EU CBRN Action Plan (2)

Goal:

- Reduce the threat and damage from CBRN incidents of accidental, natural and intentional origin, including terrorist threats (all hazard-approach)

- Contribute to the implementation of the EU Counter Terrorism Strategy

CBRN Action Plan: Prevention

- Goal 1: Develop EU lists of high-risk CBRN materials and risk-based approaches to security
- Goal 2: Enhance the security of high risk CBRN materials and facilities
- Goal 3: Enhance control over high risk CBRN materials
- Goal 4: Contribute to the development of a high security culture of staff
- Goal 5: Improve the identification and reporting of suspicious transactions and behaviour
- Goal 6: Enhance the security of transport
- Goal 7: Improve information exchange
- Goal 8: Strengthen the import/export regime
- Goal 9: Strengthen cooperation on the security of nuclear materials

CBRN Action Plan: Preparedness/Response

- Goal 1: Improve emergency planning
- Goal 2: Strengthen countermeasure capacity
- Goal 3: Improve domestic and international information flows regarding CBRN emergencies
- Goal 4: Develop improved modelling tools and strengthen decontamination and remediation capacity
- Goal 5: Improve the capacity to conduct criminal investigations

CBRN Action Plan: Prevention, Detection, Response

- Goal1: Enhance international cooperation
- Goal 2: Improve communication with the public
- Goal 3: Develop improved information tools for CBRN security
- Goal 4: Improve training
- Goal 5: Strengthen personnel security
- Goal 6: Strengthen and prioritise research
- Goal 7: Ensure the criminalisation of CBRN terrorism

Existing German Regulations

List of biological agents and toxins based on security concerns	War Weapons Control Act List, Export, List to the Council Regulation on Dual Use No. 428/2009
Permission/license/notification for/of handling biological materials	Protection against infection act, Genetic engineering act, Animal Pathogen Ordinance, Biological Safety Ordinance, Regulation implementing the CWC (Chemical Weapons Convention)
Personal reliability/security vetting	Protection against infection act, Animal Pathogen Ordinance, Genetic engineering act, Security vetting act, Security vetting identification regulation
Safe/secure storage	Biological Safety Ordinance, Technical Rule 100
Documentation	Genetic engineering documentation regulation, Biological Safety Ordinance
Access control	Biological Safety Ordinance
Transfer/hand-over	Protection against infection act, IfSG, Animal Pathogen Ordinance, Animal Pathogen Import Ordinance,
Export/import control	Foreign Trade and Payments Act, Regulation implementing the Foreign Trade and Payments Act; EU Council Regulation on Dual-use No. 428/2009, Protection against infection act, Animal Pathogen Import Ordinance,
Safe/secure transport	Law on the Carriage of Dangeous Goods, Dangerous Goods Ordinance, Road, rail and inland waterways, Regulation for the transport of dangerous goods by sea, Security vetting act, Security vetting identification regulation
Register of facilities	Protection against infection act, Animal Pathogen Ordinance, Genetic engineering act, Biological Safety Ordinance
Register of individuals	Biological Safety Ordinance, Protection against infection act, Animal Pathogen Ordinance, Security vetting act, Security vetting identification regulation

Biosecurity „Activities in Europe“

- CEN (Comité Européen de Normalisation):
  CEN Workshop Agreement (CWA)15793
  “Laboratory Biorisk Management Standard” (Feb 2008)

Biosecurity – CWA 15793 „Laboratory Biorisk Management Standard“

- 4 Biorisk management system requirements
- 4.1 General requirements
  - 4.1.1 Biorisk management system
  - 4.1.2 Continual improvement
- 4.2 Policy – Biorisk management policy
- 4.3 Planning
  - 4.3.1 Planning for hazard identification, risk assessment and risk control
  - 4.3.2 Conformity and compliance
  - 4.3.3 Objectives, targets and program
- 4.4 Implementation and operation
  - 4.4.1 Roles, responsibilities and authorities
    - 4.4.1.3 Biorisk management committee
    - 4.4.1.4 Biorisk management advisor
    - 4.4.1.6 Occupational health
    - 4.4.1.7 Facilities manager(s)
    - 4.4.1.8 Security manager
    - 4.4.1.9 Animal care manager

Biosecurity – CWA 15793 „Laboratory Biorisk Management Standard“

- 4.4 Implementation and operation
  - 4.4.2 Personnel training, awareness and compliance
    - 4.4.2.1 Qualifications, experience and aptitudes of personnel
    - 4.4.2.2 Supervision of new employees
    - 4.4.2.3 Continuity and succession planning
    - 4.4.2.4 Biorisk-related training
  - 4.4.3 Consultation and communication
  - 4.4.4 Operational control
    - 4.4.4.2 Biological agents and toxin inventory and information
    - 4.4.4.4 Change management
    - 4.4.4.5 Good microbiological technique
    - 4.4.4.6 Worker health program
    - 4.4.4.7 Behavioral factors and control of workers
    - 4.4.4.8 Infrastructure and operational management
    - 4.4.4.9 Transport of biological agents and toxins

Biosecurity – CWA 15793 „Laboratory Biorisk Management Standard“

- 4.4 Implementation and operation
  - 4.4.5 Emergency response and contingency plans
    - 4.4.5.1 Emergency scenarios
    - 4.4.5.2 Emergency plans
    - 4.4.5.3 Emergency exercises and simulations
    - 4.4.5.4 Contingency plans
- 4.5 Checking and corrective action
  - 4.5.1 Performance measurement and analysis of data
  - 4.5.2 Records, document and data control
  - 4.5.3 Inventory monitoring and control
  - 4.5.4 Accident and incident investigation, non-conformity, corrective and preventive actions
- 4.6 Biorisk management review

Regulations of the IfSG (Protection against infection act**), and the BioStoffV** (Biological Safety Ordinance), **which are consistent with the CWA 15793**

- Permit obligation for activities with pathogens (IfSG § 44)
- Examination of requirements for obtaining this permission (IfSG § 47)
- Obligation to notify activities with pathogens / biological agents (IfSG § 49, BioStoffV § 13)
- Obligation to maintain a list of workers due to work with group 3 or 4 biological agents (BioStoffV § 13)
- Obligatory supervision of the competent authority for the handling of pathogens (IfSG § 51)
- Restriction of the number of workers to what is absolutely necessary (TRBA 100, 5.1(2), 5.3(5), 5.4.1(11))
- Access of other individuals under the supervision of a trained person (TRBA 100, 5.4.1(11))
- A single individuum shall never work alone in a laboratory of protection level 4 (TRBA 100, 5.5(13))
- TRBA 120 „Versuchstierhaltung“ (keeping of laboratory animals)

Regulations of the IfSG (Protection against infection act), **and the BioStoffV** (Biological Safety Ordinance), **which are consistent with the CWA 15793**

- Safe storage of biological agents (tightly sealed – protection level 4) (BioStoffV, annex II, TRBA 100, 5.3(11))
- Obligation to perform risk assessment (BioStoffV §§ 5 – 8, TRBA 100, 4)
- Biosafety officer – BSB, ABS (GenTSV §§ 16 – 19)
- Operating instructions (BioStoffV § 12, section 1)
- Hygiene measures, protective equipment (BioStoffV § 11)
- Emergency plan (TRBA 100, 5.4.1(12))
- Instruction of the workers (BioStoffV § 12, section 2)
- Obligation to notify and to keep records (BioStoffV § 13)
- Preventive medical check-ups (BioStoffV § 15)
- Offering of vaccination for personnel working with pathogens for which vaccines are available (BioStoffV, annex IV)
- TRBA 120 „Versuchstierhaltung“ (keeping of laboratory animals)

Summary

- In Germany, all aspects of biosafety in microbiological laboratories are sufficiently and completely considered by the IfSG, the BioStoffV with its TRBA and, insofar as applicable, by the GenTG and the GenTSV
- Also, the major aspects of biosecurity in microbiological laboratories are covered by existing regulations, according to the CWA 15793
- However, some formal and organisational requirements, specific personnel structures and specific controll- and supervision measures according to CWA are not included in the mentioned laws and regulations
- This could be achieved by including a new chapter „biosecurity“ in the regulations, without introducing a new, extensive standard, which would be laboriously to implement

Outlook

- Framework is complex and disjointed
- Some conflicting regulatory requirements
- Differing regulatory philosophies and practices
- Different levels and types of inspection, enforcement and sanctions

It would be helpful to have:

- Single regulatory *framework*
- ***Common set*** of containment measures
- Single regulatory ***body, b***ased upon ***risk assessment***
- ***Integrated*** notification system